



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-1242]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Strengthening U.S. Response to Resistant Gonorrhea (SURRG) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on September 30, 2020 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Strengthening U.S. Response to Resistant Gonorrhea (SURRG) (OMB Control No. 0920-1242, Exp. 9/30/2021) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purposes of Strengthening U.S. Response to Resistant Gonorrhea (SURRG) are to: (1) improve national capacity to detect, monitor, and respond to the emerging threat of antibiotic-resistant gonorrhea, (2) understand trends in and factors contributing to antibiotic-resistant gonorrhea, and (3) build a robust evidence-base for public health action. This information collection is important because: (1) effective treatment of gonorrhea is critical to gonorrhea control and prevention, (2) untreated or inadequately treated gonorrhea can cause serious reproductive health complications, such as infertility, (3) *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) has consistently demonstrated the ability to develop resistance to the antibiotics used for treatment and may be developing resistance to the last remaining treatment option recommended by the Centers for Disease Control and Prevention (CDC), and (4) antibiotic-resistant gonorrhea is extremely difficult to detect without enhanced surveillance and public health activities, such as SURRG, because healthcare providers

rarely perform or have access to resistance testing for individual patients.

SURRG supports rapid detection of resistant gonorrhea and gets actionable information into the hands of healthcare providers (to support appropriate treatment of individual patients) and local health departments (to support rapid public health response to slow the spread of resistant infections in the community). Jurisdictions participating in SURRG applied as part of a competitive process and participate voluntarily. As an overview of SURRG, healthcare providers at participating clinics (sexually transmitted disease [STD] clinics affiliated with a single public health department or other participating non-STD clinic sites) collect specimens for *N. gonorrhoeae* culture testing from men and women seeking care for possible gonorrhea. Specimens that demonstrate *N. gonorrhoeae* (called "isolates") undergo antibiotic resistance testing within several days at a local public health laboratory. Laboratory results demonstrating resistance are rapidly communicated by the laboratory staff to the healthcare provider and designated health department staff member, who initiates a field investigation. The patient (from whom the resistant specimen was collected) is interviewed about risk factors and recent contacts, and will be re-tested to ensure that they were cured. Recent contacts are interviewed by the health department (contact tracing) and tested for gonorrhea. The participating health departments collect and transmit to CDC demographic and clinical data about persons

tested for, and diagnosed with gonorrhea in the participating clinics, results of local antibiotic resistance testing, and information about field investigations. None of the data transmitted to CDC contains any personally identifiable information.

These data are used by CDC to monitor resistance, understand risk factors for resistance, and identify the most effective approaches to prevent the spread of resistance. Data are transmitted through CDC's Secure Access Management Services (SAMS). SAMS is an approved federal information technology system that provides authorized and validated users secure and encrypted access to CDC file transfer applications. The encrypted data are stored in a secure CDC server with strictly controlled and restricted access rights. Isolates are shipped each month to one of four Antibiotic Resistance Regional Laboratory Network (ARLN) laboratories for confirmatory antibiotic susceptibility testing and molecular characterization. The isolates only contain bacterial DNA (and not human DNA).

Under the SURRG protocol, the local SURRG data managers from each of the funded jurisdictions abstract STD clinic data for patients tested for gonorrhea, receive data from non-STD clinic healthcare sites about persons tested for gonorrhea, receive resistance testing laboratory results from local public health laboratories, abstract data about field investigations, and merge the data. Every two months, the local SURRG data

manager cleans the data, removes personally identifiable information, and transmits the data to CDC. We estimate these data processes will take 16 hours every two months. Annually, the local SURRG data manager will send a final cumulative data file, so a total of seven data transmissions/responses will occur. Every two months, data managers at each of the participating non-STD clinic health centers abstract and clean data and securely transmits the data to the local SURRG data manager. We estimate that it will take three hours each time data managers at each non-STD SURRG location abstract, clean, and transmit SURRG data.

Microbiologists at public health laboratories from each of the eight SURRG funded jurisdictions conduct antibiotic resistance testing on all *N. gonorrhoeae* isolates from all STD clinic sites and non-STD clinic sites participating in SURRG. Each test takes approximately 10 minutes of staff time, and testing of control strains is also conducted approximately twice per week at each laboratory. On average, each jurisdiction conducts approximately 600 resistance tests per year for patient care, plus 100 control strains per year for quality assurance. Thus, a total of approximately 700 tests per year per grantee are performed. Every two months, a laboratory data manager abstracts test results and securely sends the datafile to the local SURRG data manager. We estimate that laboratory data managers spend approximately one hour each time they abstract, clean, and transmit project data.

Health department staff will interview: any person diagnosed with antibiotic-resistant gonorrhea or have a case of gonorrhea of public health significance index case, and their sexual contacts. On average, each jurisdiction will identify four drug-resistant isolates each month. These isolates will spur field investigations, which will result in six additional interviews each month. We estimate a total of 120 interviews will occur annually at each site, for a total across the 8 sites of 960 interviews each year. Each interview will take approximately 20 minutes.

The total estimated annual burden hours are 2,665. There are no additional costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Local SURRG data manager	Facility Data Elements	8	7	16
Data manager at non-STD clinic health centers	Non-STD clinic Data Elements	26	6	3
Public Health Laboratory Microbiologist	Laboratory Testing Data Elements	8	700	10/60
Public Health Laboratory Data Manager	Laboratory Data Elements	8	6	1
Gonorrhea Patients and Sexual Contacts	Field Investigation Data Elements	960	1	20/60

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